

REMARKS

Claims 15-20, 23-32 and 42-44 remain pending in this application. Claims 1-14, 21, 22 and 33-40 have been cancelled, without prejudice. Claim 15 is amended to more clearly claim the invention.

Claims 15-20 and 30-32 stand rejected under 35 USC §102(b) as being anticipated by US Patent No. 5480424 (“Cox”). Applicant respectfully traverses the rejection.

As amended, independent claim 15 claims a valve that includes a flexible sleeve having a proximal end, a distal end and an outside surface; at least one cusp secured to the sleeve and configured to permit blood flow through the at least one cusp in a single direction; at least one ring attached to the outside surface at only the proximal end of the sleeve, the at least one ring being attached to a portion of the sleeve that is not everted; and at least one fastener connected to the at least one ring, the at least one fastener extending in a direction radially outward with respect to the sleeve and including at least one leg.

Thus, among other elements, the claimed valve includes at least one fastener connected to a ring that is attached to the outside surface of the proximal end of a flexible sleeve. The at least one fastener extends radially outward with respect to the sleeve and includes at least one leg.

Cox on the other hand describes a valve that has an annuloplasty ring attached to the inlet end of the valve sleeve. Cox describes that the valve may be attached to the inner vessel wall using suture that is passed through the annuloplasty ring and into the vessel wall. See Cox, Summary of Invention (“the tube inlet is sutured to the mitral or tricuspid valve annulus”); Cox, column 18, lines 10-15 (“The inlet (proximal) 202 end of the tubular segment 200 is sutured into the mitral valve annulus 121, using a suture line 204 which travels around the entire circumference of the annulus 121 and the tubular segment 200. If desired, an annuloplasty ring (such as illustrated in FIG. 8) can be used to create a bridge between the valve annulus 121 and the SIS tissue inlet 202.”)

Cox does not describe affixing the valve to the native tissue by a means other than suture. As a result, Cox clearly does not describe a valve having at least one fastener that extends radially outward with respect to the sleeve and includes at least one leg. Applicant therefore submits that Cox fails to teach the elements of the claimed invention, and requests that the rejection be withdrawn.

Claims 23-26 stand rejected under 35 USC §103(a) as being unpatentable over Cox as applied to claim 15, and further in view of US Patent No. 5840081 (“Andersen”). Applicant respectfully traverses the rejection.

First, Applicant submits that claims 23-26 and claim 15, as amended, and the claims that depend therefrom are not described by the combination of Cox and Andersen. Neither Cox or Andersen describe a valve that is affixed to the native tissue that has at least one ring and at least one fastener connected to the ring, wherein the at least one fastener extends in a direction radially outward with respect to the sleeve and includes at least one leg. As stated above, Cox only teaches an annuloplasty ring that is sutured to the native tissue or directly suturing the valve to the native suture. Andersen describes a stent structure that is attached to a valve at its commissural points. Andersen is affixed to the native tissue by expanding the stent structure using a balloon. Thus, because neither Cox nor Andersen describe the valve of claim 15, then the combination fails to describe any claim that depends from claim 15.

Second, the Examiner states that in making the combination of Cox and Andersen that it would have been obvious to substitute the “ring” of Andersen for the basic structure of Cox. Applicant disagrees as one skilled in the art would not substitute Andersen’s ring or stent for the structure in Cox as Cox teaches away from such a combination.

Specifically, Cox teaches away from the use of a stent to attach a valve to the native tissue. In the Objects of the Invention, Cox states: “Another object of this invention is to provide a method of using tubular starting material to create a replacement heart valve **without requiring**

the use of a foreign object such as a stent to secure the replacement valve in position.” Cox states definitively at column 21:10-29 that the invention described therein do not require stents:

It should be noted that the tubular valves of this invention do not require stents. As used herein, the term "stent" includes any man-made device (other than a suture, annuloplasty ring, or leaflet material) which is surgically implanted in a patient's heart (or aorta or pulmonary artery) as part of a replacement valve, and which is contacted by blood which flows through the heart (or aorta or pulmonary artery). Stents are major components in all mechanical replacement valves, since they must securely hold the ball, flapper, or other movable elements of the valve in proper position; they are also used in nearly every type of artificial tissue valve, to secure the tissue flaps in the proper configuration. The term "stent" does not include reinforcing pledges placed on the outside of an aorta or pulmonary artery, since such pledges would not be contacted by blood flowing through the artery.

Stents *are known to increase turbulence and thrombosis.* Since the valves disclosed herein are stentless, this invention offers an important advance over prior art replacement valves which are currently approved by the FDA.

Thus, Cox teaches away from using stents as they are known to increase turbulence and thrombosis.

Applicants thus submit that the combination of Cox and Andersen fails to describe claim 15 and the claims that depend therefrom, and that the combination is improper as one skilled in the art would not have made such a combination at the time of the invention. As a result, Applicant seeks withdrawal of the rejection.

Claims 27-29 and 42-44 stand rejected under 35 USC §103(a) as being unpatentable over Cox as modified by Andersen as applied to claim 15, and further in view of US Patent No. 5489295 ("Piplani"). Applicant respectfully traverses the rejection.

Applicant submits above that the combination of Cox and Andersen is improper and thus the additional combination of Piplani also is improper as to claim 15, as amended, and those claims that depend therefrom. Further, Applicant submits that at least claims 26-28 are not described by any combination of Cox, Andersen and Piplani. In particular, Piplani does not

describe a valve having at least one fastener comprise a series of legs arranged circumferentially about the ring (claim 26); a valve having a ring with a longitudinal axis and the at least one fastener comprises at least one mounting pin attached to the ring, the mounting pin having two ends offset from one another in the longitudinal direction (claim 27) or a valve wherein the two ends of the at least one mounting pin extend radially outward from the mounting ring (claim 28). It should be noted as well that the connecting structure 163 of Piplani resides on the inside of the sleeve rather than being attached on the outside surface of the sleeve. See Figure 4.

As discussed above, Cox and Andersen fail to teach or suggest the invention claimed in claim 15. For at least the same reasons discussed above, the above proposed combination of Cox, Andersen and Piplani also fails to show the claimed elements of claims 27-29 and 42-44. As a result, Applicant requests that the rejection be withdrawn.

Applicant grants the PTO permission to charge the deposit account no. 10-0750/BST/HRT0287 for any fees or charges related to this application. Applicant respectfully requests the Examiner to contact the below-signed if a discussion regarding the merits would advance prosecution of this case.

Respectfully submitted,

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